SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 7 2000 K001707

Performance Characteristics

A. Comparison Testing

A total of four hundred and sixty-two sera were tested for the presumptive presence of toxoplasma IgM antibodies using the Diamedix Is-Toxoplasma IgM Capture Test Kit and other legally marketed tests at two independent sites (site #1, California and site #2, New York) as well as at Diamedix Corp., Miami, FL (site #3). At site #3 testing was performed both manually and using the MAGO Plus Automated EIA Processor. Toxoplasma IgG antibody data was also available for a number of the samples tested.

Site #1, a large commercial clinical laboratory in California, not affiliated with the manufacturer, tested 121 samples. These samples consisted of 101 fresh samples submitted to the laboratory for Toxoplasma IgM antibody testing as well as 20 frozen samples with positive IgM antibody status. Samples were obtained nationwide. For the fresh samples, 32 were from males and 69 from females with ages ranging from 3 days to 66 years old. Of the samples tested 19 of the 20 frozen positive samples were also positive for Toxoplasma IgG antibodies. Of the 101 fresh samples 71 had also been tested for Toxoplasma IgG. Of these, 10 were positive and 61 were negative. TABLE 1 shows the results obtained for the Is-Toxoplasma IgM Capture Test Kit and their currently used IFA testing method. This table also denotes the Toxoplasma IgG results for the samples

Site #2, a commercial reference laboratory in New York, not affiliated with the manufacturer, tested 121 samples. These samples consisted of 50 fresh samples and 50 frozen samples submitted to the laboratory for Toxoplasma IgM screening. Samples were obtained from various regions. This sample population was supplemented with 21 frozen samples procured from a vendor based on their positive serostatus. This positive serostatus was based on the results of another IgM test and not on documented clinical disease. Twenty-eight of the samples were from males and 79 from females with the remainder unidentified as regards gender. Of the female population (non-vendor samples) 52 were identified as prenatal samples. Patient ages ranged from 3 days to 80 years old. Toxoplasma IgG data was available for vendor samples. TABLE 2 shows the results obtained for the Is-Toxoplasma IgM Capture Test Kit and their currently used EIA testing method. TABLE 2a shows the comparative results for the prenatal samples only.

TABLE 1

Is-Toxoplasma IgM Capture - Site #1

IFA	Positive	Negative	Equivocal
Positive	21 [20/20]	5 [2/5]	0
Negative	0	94 [10/71]	1
*Equivocal	0	0	0

		95% CI**
Overall Agreement	115/120 = 95.8%	90.5-98.6

TABLE 2

Is-Toxoplasma IgM Capture - Site #2

Other EIA	Positive	Negative	Equivocal
Positive	7 [6/21]	5 [5/21]	5 [5/21]
Negative	1	102	0
*Equivocal	1	0	0

		95% CI **
Overall Agreement	109/115 = 94.8%	89.0-98.1

TABLE 2a - Prenatal Samples

Is-Toxoplasma IgM Capture- Site #2

Other EIA	Positive	Negative	Equivocal
Positive	0	0	0
Negative	0	52	0
*Equivocal	0	0	0

Overall Agreement 52/52 = 100.0%
95% CI** 93.2-100.0

* Equivocal results were excluded from calculations ** 95% Confidence Intervals (CI) calculated by the Exact Method (11).

[ ] denotes the number of samples positive for IgG /number tested for IgG

For Site #1, the 5 samples that were negative in the Is-Toxoplasma IgM Capture Test Kit and positive by IFA all had titers of 1:20, the minimum positive titer. Further testing of these discordant samples was performed by assaying them using a referee capture EIA method. Two of the samples were negative, two were equivocal and one weakly positive when tested with a referee capture EIA method.

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For Site #2, further testing of the six discordant samples was performed in a similar manner. Of the 5 samples negative in the Is-Toxoplasma IgM Capture and positive by the other EIA, four were weakly positive and one was negative in a referee EIA capture method. The sample that was positive in the Is-Toxoplasma IgM Capture and negative by the other EIA was negative in the referee EIA capture method. All discrepancies occurred with the samples procured from a vendor.

Site #3 (Diamedix Corp.) tested 220 samples (all frozen) by the manual and MAGO Plus methods. Of these samples 111 were obtained from the normal S. Florida blood donor population. In addition, ninety-nine defined seropositive samples were obtained from a hospital located in Italy specializing in the prevention of congenital diseases. Ninety-seven of these samples were also positive for IgG antibodies. Of these samples, sixty-eight were from pregnant women (sixty-six of these samples were positive for IgG antibodies). The remaining ten samples were from a commercially obtained reference panel. All ten were positive for IgG antibodies. TABLE 3 show the results obtained for the normal population and TABLE 4 shows the results for the positive population using the Is-Toxoplasma IgM Capture Test Kit compared to another marketed capture EIA method. TABLE 4a shows the performance of the prenatal samples.

TABLE 3

Normal Population - Site #3 : Manual Is-Toxoplasma IgM Capture

Other Capture EIA	Positive	Negative	Equivocal
Positive	0	0	0
Negative	1	110	0
*Equivocal	0	0	0

		**95% CI
Relative Specificity	110/111 = 99.1%	95.1-100.0
Overall Agreement	110/111 = 99.1%	95.1-100.0

TABLE 4

Positive Population - Site #3 : Manual Is-Toxoplasma IgM Capture

	Positive	Negative	Equivocal
Positive	93 [93]	3 [3]	6 [6]
Negative	1 [1]	6 [6]	0
*Equivocal	0	0	0

		**95% CI
Overall Agreement	99/103 = 96.1 %	90.4-98.9

TABLE 4a- Prenatal Samples

Is-Toxoplasma IgM Capture - Site #3

	Positive	Negative	Equivocal
Positive	60 [58]	2 [2]	3[3]
Negative	1 [1]	2 [2]	0
*Equivocal	0	0	0

Overall Agreement 62/65 = 99.1%
** 95% CI 95.1-100.0

* Equivocal results were excluded from calculations
** 95% Confidence Intervals (CI) calculated by the Exact Method (11)
[ ] denotes the number of samples positive for IgG

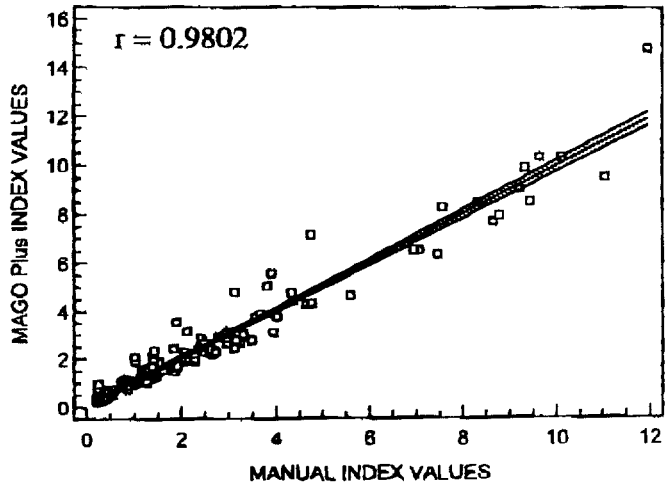
For Site #3, further testing of the 5 discordant sera revealed that the 3 sera negative in the Is-Toxoplasma IgM Capture Test Kit but positive in the other capture EIA were negative by a referee EIA method. The 2 sera that were positive in the Is-Toxoplasma IgM Capture Test Kit and negative in the other capture EIA were negative by the referee method.

NOTE: Please be advised that 'relative' refers to the comparison of the assay's results to that of a similar assay. There was not an attempt to correlate the assay's results with disease presence or absence. No judgment can be made on the comparison assay's accuracy to predict disease.

B. Correlation of Manual and MAGO Plus Results

The Is-Toxoplasma IgM Capture Test Kit has been developed for automated as well as manual use. To demonstrate the equivalence of the procedures, the results of the 220 samples tested manually and using the MAGO Plus were compared. A scattergram and regression line of the results obtained with 95% confidence intervals is shown in FIGURE 1. The correlation coefficient (r) was 0.9802.

FIGURE 1 : Manual vs MAGO Plus Correlation



C. CDC Serum Panel Data

The following information is from a serum panel obtained from the CDC and tested by Diamedix. The results are presented as a means to convey further information on the performance of this assay with a masked charactized panel. This does not imply an endorsement of the assay by the CDC.

The panel consists of 32% true positive samples and 65% true negative samples. The Diamedix is-Toxoplasma IgM Capture Test Kit demonstrated 99% total agreement with the CDC results. Of the results obtained by Diamedix there was 100% (32/32) agreement with the true positive specimens and 98.5% (64/65) agreement with the true negative specimens.

D. Cross-Reactivity / Interference Studies

The specificity of the Is-Toxoplasma IgM Capture Test Kit was validated by testing a number of sera containing relatively high levels of IgM antibody to other viruses as determined using commercially available test kits. A total of 26 known IgM positive sera were tested. In addition, the effect of potential interference from rheumatoid factor (RF), anti-nuclear antibody (ANA), viral-specific IgG and heterophile antibodies was assessed by testing an additional 23 sera. These data are shown in TABLE 5. TABLE 6 shows the lack of interference in samples containing high levels of IgG antibodies and low levels of IgM antibodies before and after the removal of the IgG.

TABLE 5

Specificity	# of Positive Samples	# Positive in the Is-Toxo IgM Capture
EBV IgM	8	0
Lyme IgM	3	0
CMV IgM	5	0
HSV IgM	5	0
Rubella IgM	5	0
Heterophile Antibody	4	0
RF	5	0
ANA	10	0
Toxoplasma IgG	4	0

TABLE 6

	Before IgG Removal		After IgG Removal	
Sample #	IgG Index	IgM Index	IgG Index	IgM Index
1	3.99	1.81	0.00	1.65
2	3.65	1.65	0.00	1.69
3	4.12	1.51	0.01	1.54
4	1.42	2.42	0.05	2.36
5	4.99	3.46	0.13	1.97
6	3.82	1.63	0.00	1.78
7	3.90	1.41	0.08	1.70
8	4.48	2.18	0.07	2.48
9	2.16	2.50	0.00	2.67
10	3.04	1.25	0.00	1.46

IgG Pos ≥ 1.00 IgM Pos ≥ 1.10

E. Verification of IgM Specificity

To confirm that the Is-Toxoplasma IgM Capture Test Kit specifically detects IgM-class antibodies, 13 samples with high levels of Toxoplasma IgM antibodies were selected for testing. These samples were treated with 20 mM dithiothreitol (DTT) to destroy the IgM and were then retested in the Is-Toxoplasma IgM Capture Test Kit. The results in TABLE 7 show that these samples were rendered negative when treated with DTT confirming the specificity of the Is-Toxoplasma IgM Capture test kit for detecting IgM-class antibodies.

TABLE 7

	Untreated		Treated with 20 mM DTT	
	Is-Toxo IgM Capture		Is-Toxo IgM Capture	
Sample #	Index	Interp	Index	Interp
1	6.53	POS	0.37	NEG
2	3.43	POS	0.27	NEG
3	9.60	POS	0.44	NEG
4	2.71	POS	0.26	NEG
5	5.47	POS	0.24	NEG
6	5.92	POS	0.24	NEG
7	7.51	POS	0.33	NEG
8	2.75	POS	0.20	NEG
9	1.73	POS	0.23	NEG
10	6.57	POS	0.29	NEG
11	2.84	POS	0.62	NEG
12	7.31	POS	0.29	NEG
13	4.43	POS	0.24	NEG

F. Precision

Six serum samples, as well as the kit Controls, were tested to assess the precision of the Is-Toxoplasma IgM Capture Test Kit. Sites #1 and #2 tested samples in triplicate in three separate runs on three different days. Site #3 (Diamedix Corp.) tested samples in triplicate in two separate runs on three different days both manually and using the MAGO Plus Automated EIA Processor. The results obtained are shown in TABLES 8-11.

TABLE 8 : Site #1 - Intra-Assay and Interassay Precision

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=9)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
T1	0.211	0.018	8.53	0.187	0.018	9.63	0.191	0.004	2.09	0.196	0.017	8.67
T2	0.241	0.006	2.49	0.229	0.013	5.68	0.261	0.019	7.28	0.244	0.018	7.38
T3	1.761	0.087	4.94	1.826	0.027	1.48	1.714	0.092	5.37	1.767	0.081	4.58
T4	1.668	0.049	2.94	1.942	0.069	3.55	1.815	0.042	2.31	1.808	0.128	7.08
T5	2.838	0.157	5.53	3.296	0.114	3.46	3.014	0.099	3.28	3.049	0.228	7.48
T6	3.498	0.062	1.77	3.866	0.066	1.71	3.498	0.081	2.32	3.620	0.194	5.36
LPC	1.390	0.035	2.52	1.650	0.042	2.55	1.450	0.015	1.03	1.497	0.121	8.08
NC	0.279	0.031	11.11	0.230	0.013	5.65	0.262	0.011	4.20	0.257	0.028	10.89

TABLE 9: Site #2 - Intra-Assay and Interassay Precision

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=9)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
T1	0.296	0.053	17.91	0.416	0.072	17.31	0.181	0.029	16.02	0.297	0.112	37.71
T2	0.298	0.062	20.81	0.465	0.044	9.46	0.290	0.040	13.79	0.351	0.096	27.35
T3	1.796	0.054	3.01	1.449	0.024	1.66	1.896	0.047	2.48	1.714	0.207	12.08
T4	1.991	0.116	5.83	1.735	0.092	5.30	1.963	0.038	1.94	1.896	0.144	7.59
T5	3.312	0.134	4.05	2.528	0.224	8.86	3.388	0.086	2.54	3.076	0.435	14.14
T6	4.128	0.224	5.43	3.604	0.085	2.36	3.797	0.176	4.64	3.843	0.273	7.10
CAL	0.998	0.122	12.22	1.143	0.141	12.34	1.142	0.030	2.63	1.094	0.119	10.88
LPC	1.554	0.128	8.24	1.549	0.108	6.97	1.516	0.075	4.95	1.540	0.093	6.04
NC	0.260	0.044	16.92	0.429	0.080	18.65	0.241	0.037	15.35	0.310	0.102	32.90

TABLE 10 Site #3-Intra-Assay and Interassay Precision (Manual)

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=18)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A	0.226	0.016	7.08	0.248	0.019	7.66	0.213	0.026	12.21	0.229	0.025	10.92
B	0.312	0.046	14.74	0.283	0.033	11.66	0.268	0.025	9.33	0.287	0.039	13.59
C	1.874	0.021	1.12	1.861	0.077	4.14	1.912	0.089	4.65	1.882	0.069	3.67
D	1.983	0.068	3.43	1.993	0.110	5.52	2.025	0.089	4.40	2.000	0.087	4.35
E	3.331	0.089	2.67	3.260	0.100	3.07	3.423	0.142	4.15	3.338	0.126	3.77
F	3.895	0.308	7.91	4.286	0.420	9.80	4.284	0.175	4.08	4.274	0.258	6.04
c/o CAL	1.080	0.037	3.43	1.028	0.026	2.53	1.051	0.043	4.09	1.053	0.040	3.80
LPC	1.661	0.061	3.67	1.703	0.120	7.05	1.740	0.072	4.14	1.701	0.089	5.23
NC	0.290	0.036	12.41	0.314	0.035	11.15	0.271	0.013	4.80	0.291	0.033	11.34

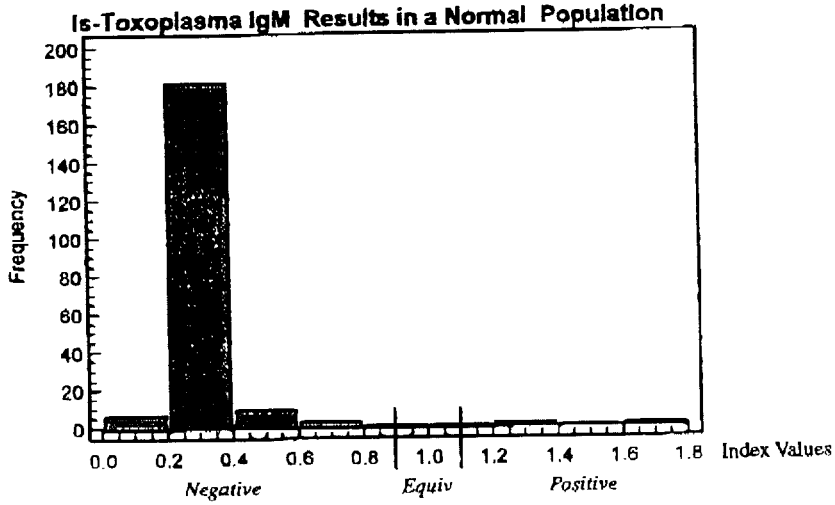
TABLE 11 : Site #3- Intra-assay and Interassay Precision (MAGO Plus)

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=18)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A	0.34	0.027	7.94	0.35	0.050	14.29	0.31	0.129	41.61	0.33	0.079	23.65
B	0.41	0.073	17.80	0.46	0.054	11.74	0.35	0.044	12.57	0.40	0.069	17.08
C	1.68	0.065	3.87	1.77	0.081	4.58	1.88	0.196	10.43	1.77	0.147	8.30
D	2.07	0.448	21.64	2.05	0.108	5.27	2.16	0.152	7.04	2.09	0.268	12.80
E	3.40	0.430	12.65	3.41	0.261	7.65	3.84	0.303	7.89	3.55	0.382	10.77
F	3.90	0.308	7.90	4.22	0.197	4.67	4.94	0.379	7.67	4.35	0.533	12.25
c/o CAL	1.16	0.094	8.10	1.02	0.067	6.57	1.15	0.126	10.96	1.11	0.113	10.16
LPC	2.11	0.543	25.73	1.71	0.206	12.05	2.00	0.456	22.80	1.94	0.436	22.49
NC	0.44	0.117	26.59	0.43	0.052	12.09	0.43	0.168	39.07	0.44	0.107	24.37

Expected Values

The prevalence of Toxoplasma infection can vary depending on a number of factors such as age, gender, geographical location, socio-economic status, race, type of test used, specimen collection and handling procedures, and clinical and epidemiological history of individual patients. The prevalence of Toxoplasma infection in the USA is in the range of less than 1 - 3% (13, 14,15). In the present study two hundred sera from S. Florida blood donors were evaluated in the Is-Toxoplasma IgM Capture Test Kit. Of these samples, one hundred and ninety-eight (99%) were negative and two (1%) were positive. TABLE 12 shows the age and prevalence profile of this population. FIGURE 2 shows a distribution of Index values obtained for this population.

FIGURE 2



(Note that the magnitude of the Index Value has no significance)

TABLE 10 Site #3-Intra-Assay and Interassay Precision (Manual)

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=18)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A	0.226	0.016	7.08	0.248	0.019	7.66	0.213	0.026	12.21	0.229	0.025	10.92
B	0.312	0.046	14.74	0.283	0.033	11.66	0.268	0.025	9.33	0.287	0.039	13.59
C	1.874	0.021	1.12	1.861	0.077	4.14	1.912	0.089	4.65	1.882	0.069	3.67
D	1.983	0.068	3.43	1.993	0.110	5.52	2.025	0.089	4.40	2.000	0.087	4.35
E	3.331	0.089	2.67	3.260	0.100	3.07	3.423	0.142	4.15	3.338	0.126	3.77
F	3.895	0.308	7.91	4.286	0.420	9.80	4.284	0.175	4.08	4.274	0.258	6.04
c/o CAL	1.080	0.037	3.43	1.028	0.026	2.53	1.051	0.043	4.09	1.053	0.040	3.80
LPC	1.661	0.061	3.67	1.703	0.120	7.05	1.740	0.072	4.14	1.701	0.089	5.23
NC	0.290	0.036	12.41	0.314	0.035	11.15	0.271	0.013	4.80	0.291	0.033	11.34

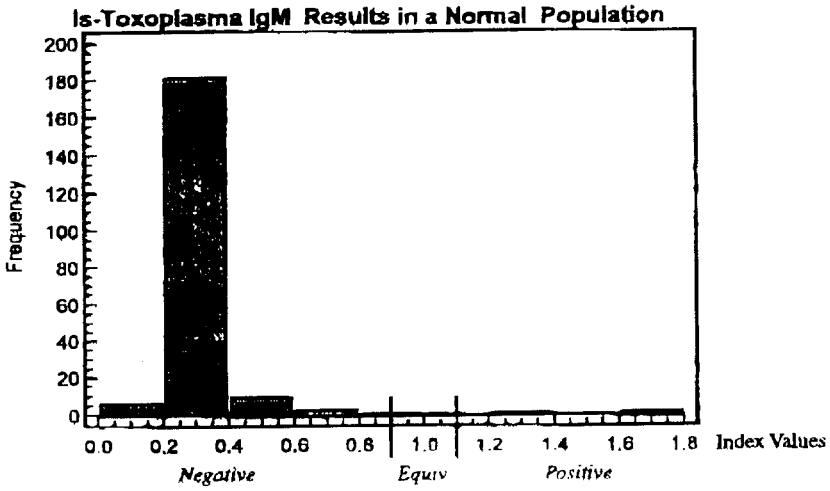
TABLE 11 : Site #3- Intra-assay and Interassay Precision (MAGO Plus)

SERUM	INTRA-ASSAY DAY 1			INTRA-ASSAY DAY 2			INTRA-ASSAY DAY 3			INTERASSAY (n=18)		
	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%	MEAN INDEX	SD	CV%
A	0.34	0.027	7.94	0.35	0.050	14.29	0.31	0.129	41.61	0.33	0.079	23.65
B	0.41	0.073	17.80	0.46	0.054	11.74	0.35	0.044	12.57	0.40	0.069	17.08
C	1.68	0.065	3.87	1.77	0.081	4.58	1.88	0.196	10.43	1.77	0.147	8.30
D	2.07	0.448	21.64	2.05	0.108	5.27	2.16	0.152	7.04	2.09	0.268	12.80
E	3.40	0.430	12.65	3.41	0.261	7.65	3.84	0.303	7.89	3.55	0.382	10.77
F	3.90	0.308	7.90	4.22	0.197	4.67	4.94	0.379	7.67	4.35	0.533	12.25
c/o CAL	1.16	0.094	8.10	1.02	0.067	6.57	1.15	0.126	10.96	1.11	0.113	10.16
LPC	2.11	0.543	25.73	1.71	0.206	12.05	2.00	0.456	22.80	1.94	0.436	22.49
NC	0.44	0.117	26.59	0.43	0.052	12.09	0.43	0.168	39.07	0.44	0.107	24.37

Expected Values

The prevalence of Toxoplasma infection can vary depending on a number of factors such as age, gender, geographical location, socio-economic status, race, type of test used, specimen collection and handling procedures, and clinical and epidemiological history of individual patients. The prevalence of Toxoplasma infection in the USA is in the range of less than 1 - 3% (13, 14,15). In the present study two hundred sera from S. Florida blood donors were evaluated in the Is-Toxoplasma IgM Capture Test Kit. Of these samples, one hundred and ninety-eight (99%) were negative and two (1%) were positive. TABLE 12 shows the age and prevalence profile of this population. FIGURE 2 shows a distribution of Index values obtained for this population.

FIGURE 2



(Note that the magnitude of the Index Value has no significance)

TABLE 12

	Number of Donors	% Seronegative	% Seropositive	% Equivocal
Total Number	200	99.0% (198)	1.0% (2)	0.0% (0)
Geographic Location:				
S. Florida	200			
Age				
10-19	18	100.0% (18)	0.0% (0)	0.0% (0)
20-29	47	97.9% (46)	2.1% (1)	0.0% (0)
30-39	74	100.0% (74)	0.0% (0)	0.0% (0)
40-49	40	97.5% (39)	2.5% (1)	0.0% (0)
50-59	11	100.0% (11)	0.0% (0)	0.0% (0)
60-69	9	100.0% (9)	0.0% (0)	0.0% (0)
>70	1	100.0% (1)	0.0% (0)	0.0% (0)
Gender				
Male	98	99.0% (99)	1.0% (1)	0.0% (0)
Females	102	99.0% (99)	1.0% (1)	0.0% (0)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 7 2000

Lynne Stirling, Ph.D.
Vice President, Regulatory Affairs
Diamedix
2140 North Miami Avenue
Miami, Florida 33127

Re: K001707
Trade Name: Diamedix Is-Toxoplasma IgM Capture Test System
Regulatory Class: II
Product Code: LGD
Dated: June 2, 2000
Received: June 5, 2000

Dear Dr. Stirling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix G. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(K) NUMBER : _____

DEVICE NAME : Is-Toxoplasma IgM CaptureTest System

Indications for Use : The Diamedix Is-Toxoplasma IgM Capture Test Kit is a capture enzyme Immunoassay (EIA) for the presumptive qualitative detection of IgM antibodies to *Toxoplasma gondii* in human serum. When performed in conjunction with an anti-Toxoplasma gondii IgG assay, the Is-Toxoplasma IgM Capture assay can be used as an aid in the presumptive diagnois of acute, recent or reatcivatioed Toxoplasma gondii infection. These reagents can be used either manually or in conjunction with the MAGO® Plus Automated EIA Processor. Performance has not been established in newborns. This product has not been cleared/approved by the FDA for blood/plasma donor screening.

Woody Dubois

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